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Request for grant of a patent

The Patent Office
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1	Your reference	SPG/P36086
2	Patent application number	05 JUN 1999 **9913047.8**
3	Full name, address and postcode of the applicant Patents ADP number State of incorporation	ML Laboratories plc Blaby Hall Church Street BLABY LE8 4FA 7436405001 Rdes England & Wales
4	Title of the invention	Inhaler
5	Name of agent Address for service Patents ADP number	Harrison Goddard Foote Belmont House ~~20 Wood Lane~~ Tower House Merrion Way ~~Headingley~~ ~~Leeds~~ Leeds ~~LS6 2AE~~ LS2 8PA 14571001 Rdes

6	Priority applications	Country	Priority App No	Date of Filing

Patents Form 1/77

7	Parent application (eg Divisional)	Earlier Application No	Date of Filing
8	Statement of Inventorship Needed?		
9	Number of sheets for any of the following (not counting copies of same document)		
	Continuation sheets of this form		
	Description	**6**	
	Claims	**2**	
	Abstract		
	Drawings	**2 + 2** 14	
10	Number of other documents attached		
	Priority documents		
	Translations of priority documents		
	P7/77		
	P9/77	**Yes**	
	P10/77		
	Other documents		
11	I/We request the grant of a patent on the basis of this application.		
	Signature S.P. Gilholm	Date 4 Jun 1999	
12	Name and daytime telephone number of person to contact in the United Kingdom	STEVE GILHOLM +44 113 2258350	

INHALER

This invention relates to a novel form of inhaler.

In particular the invention provides a dry powder inhaler which is adapted to be moisture resistant and/or provides improved air flow through the device.

Dry powder inhalers are known, such as CLICKHALER, produced by Innovata Biomed in the UK. Such a device is described in European Patent No 0 539 469. Moisture contamination of dry powder inhalers has long been held to be undesirable since the dry powder medicament may become clogged, creating problems in delivering correct dosages of medicament. Furthermore, some medicaments are themselves inherently moisture sensitive. Therefore, there has long been a desire to provide a dry powder inhaler that is resistant to moisture, that is, one that protects a medicament reservoir from moisture contamination either from the environment or from exhalation by a patient using the device.

We have now developed a dry powder inhaler that overcomes or mitigates this problem.

According to the invention we provide a dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the inhaler is provided with means for preventing moisture from coming into contact with medicament in the reservoir.

Moisture is prevented from coming into contact with the medicament by a sealing mechanism. In a preferred embodiment, the sealing mechanism of the inhaler will operate by the inhaler being adapted to move from an inoperable position, in which the medicament reservoir is sealed, to an operative position, in which the seal is

reversibly broken so that measurement and/or delivery of a dose of medicament may take place. The sealing mechanism will generally comprise a resilient sealing member positioned at the end of the reservoir adjacent the metering member. Furthermore, the metering member is preferentially biased towards the resilient sealing member to improve the seal provided. Preferably the resilient sealing member is in a fixed position whilst the metering member moves from an inoperable to an operable position and thus from a sealing to a non-sealing position.

The resilient sealing member preferably comprises a cover adapted to fit the base of the medicament reservoir, the sealing member being provided with an aperture to permit transmission of the medicament. The resilient sealing member may comprise any conventionally known material, for example a natural or synthetic rubber, a silicon or a PTFE material, although other similar materials can be contemplated within the scope of this invention

In an especially preferred embodiment the metering member is rotatable from an operable to an inoperable position. The metering member comprises one or more, measuring chambers adapted to measure a predetermined dosage of medicament. Thus, in the operable position, the position of measuring chamber of the metering member corresponds with the aperture in the resilient sealing member. In the inoperable position the wall surrounding the metering chamber corresponds with the aperture in the resilient sealing member thus providing a moisture tight seal.

A preferred metering member is a frusto conical member such as described in European Patent No 0 539 469. Thus, the metering member may comprise a frusto conical side wall containing measuring chamber or chambers. Such a side wall can, preferably, include a plurality of spaced-apart measuring chambers.

The use of the frusto-conical shape in the wall of the metering member containing the measuring chambers allows a good seal to be obtained between the metering member and a seat against which the frusto-conical wall mates

In a preferred embodiment the frusto conical metering member may itself comprise a combination of a frusto conical dispensing member and a frusto conical moisture resistant sleeve which forms a snug fit over the dispensing member. The moisture resistant sleeve may itself be moveable eg rotatable from a sealing to a non-sealing position as herein before described. Such a moisture resistant sleeve may comprise any conventionally known material but is preferentially a plastics material eg the same material as the metering member.

The dispensing member and the moisture resistant sleeve can, preferentially, be adapted so as to act together as a medicament measuring/dispensing member. The preferred metering member comprises a dispensing member provided with one or more dispensing chambers and a moisture resistant sleeve provided with one or more dosage measuring chambers. Preferably the metering member comprises a plurality of dispensing chambers and a plurality of measuring chambers, it is especially preferred that the metering member comprises an equivalent number of dispensing chambers to measuring chambers.

Thus, in operation, the device may be moved to a first position in which the medicament is transferred to a first measuring chamber in the moisture resistant sleeve, the device is then moved to a second position in which medicament is transferred from the measuring chamber to a dispensing chamber in the dispensing member and then to a third position where medicament is delivered to the inhalation passage.

The dispensing member may be a conventionally known member such as a frusto conical member described herein and in EP 0 539 469. However, we have also found the use of a moisture resistant sleeve permits a dispensing chamber to be provided with an air inlet. Previously, the use of an air inlet was felt to be undesirable since it might effect the accuracy of the measurement of the medicament dose. However, by use of a system wherein the medicament is first transferred to a measuring chamber,

the chamber in the dispensing member may be provided with an air inlet without any loss in accuracy of the dosage delivered. Furthermore, improved air flow provides greater likelihood of complete emptying of the dispensing chamber.

Thus according to an alternative feature of the invention we provide a dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the metering member comprises a measuring member adapted to measure a pre-defined dosage of medicament and moveable from a measuring to a non-measuring position; and a dispensing member adapted to receive the measured dosage of medicament from the measuring member and to deliver the medicament to the inhalation passage, the dispensing member being moveable from a medicament receiving position to a medicament delivering position.

In the preferred embodiment the dispensing member is provided with one or more medicament dispensing chambers, e.g. cups, said chambers being provided with an air passage so as to provide a flow of air through the air passage and the chamber into the inhalation passage upon operation of the device.

By the term dry powder we mean a medicament in finely divided form.

The invention will now be described by way of example only and with reference to the accompanying drawings in which:

Figure 1 is a perspective view of an inhalation device of the invention; and

Figure 2 is a schematic representation of the sealing and measuring mechanism.

With reference to Fig 1, a dry powder inhaler (1) comprises a medicament reservoir (2) comprising an essentially conical member; an inhalation passage (3) and a metering member (4). The inhalation passage (3) is connected to the medicament

reservoir (2) by a reservoir support (5) and is itself connected to recess (6) which provides a seat for the metering member (4). The metering member (4) is rotatable about an axis (7) from a medicament receiving position, to a medicament delivery position and then to an emptying position to allowing any residual medicament to be emptied into a waste box (8).

The recess (6) is essentially frusto conical in shape to enable it to provide a seal for the metering member (4). The metering member (4) comprises a frusto conical moisture resistant sleeve (9) which forms a snug fit between recess (6) and a dispensing member (10). The dispensing member (10) is also provided with a back plate (11).
The moisture resistant sleeve (9) abuts against the resilient seal (9a) to form a moisture resistant seal.

The moisture resistant sleeve (9) is also provided with a plurality of measuring chambers which comprise apertures (12) dimensioned to measure a predetermined amount of medicament and to fit over chambers (13) in the dispensing member (10). In a preferred embodiment, each of the chambers (13) are also provided with an air inlet (14). The medicament reservoir (2) is also provided with a moisture resistant, eg foil, cover (15) at it's end (16) distal from the metering member (4).

With reference to Figure 2, in which Figure 2a the metering device is in a closed position,

Figure 2b the metering device is in a measuring position,

Figure 2c the metering device is in a seal transitory position,

Figure 2d the metering device is in a medicament transfer position,

Figure 2e the metering device is in a medicament delivery position; and

Figure 2f the metering device is returned to the closed position.

In Figure 2a the metering device 4 is in the closed position and the medicament reservoir (2) is isolated and a seal formed between the sealing member (17) and the

surface (18) of the moisture resistant sleeve (9). In Figure 2b, the moisture resistant sleeve (9) is rotated in an anti clockwise direction so that the aperture (12) corresponds with the aperture (19) in the sealing member (17). The aperture (19) forms a cup with the surface (20) of the dispensing member (10).

In Figure 2c the moisture resistant sleeve (9) is further rotated so that the aperture (19) sits below the sealing member (17). The internal edge (21) of the sealing member (17) scrapes any excess medicament from the aperture (19) to leave a measured dose.

In Figure 2d the dispensing member (10) is rotated in an anticlockwise direction so that the dispensing chamber (13) corresponds with the aperture (12) allowing medicament to transfer from the aperture (12) to the dispensing chamber (13).

In Figure 2e both the dispensing member (10) and the moisture resistant sleeve (9) are rotated anticlockwise to expose them and the medicament to the inhalation passage (3). The patient can then inhale the medicament.

In Figure 2f the inhalation device remains in the closed position ready for use.

A variety of mechanisms may be used for the operation of the inhaler. One preferred mechanism is for movement from the closed to the measuring position to be achieved by removal of a mouth piece which is operably linked to the moisture resistor. Movement from the measuring position to the transitory position would use a mechanism similar to that described in EP 0 539 469, e.g. by depressing the button half way. Movement to the transfer position being achieved by further depressing the button, and then depression completely, moving the metering cone and the moisture resistor to the delivery position.

CLAIMS

1. A dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the inhaler is provided with means for preventing moisture from coming into contact with medicament in the reservoir.

2. A dry powder inhaler according to Claim 1 wherein the means for the prevention of moisture comprising a sealing mechanism.

3. A dry powder inhaler according to Claim 2 wherein the sealing mechanism is adapted to move from an inoperable position in which the medicament reservoir is sealed, to an operable position in which the seal is broken so that measurement and/or delivery of a dose of medicament may take place.

4. A dry powder inhaler according to Claim 2 wherein the sealing mechanism comprises a resilient sealing member positioned at the end of the medicament reservoir adjacent the metering member.

5. A dry powder inhaler according to Claim 4 wherein the metering member is biased towards the sealing member.

6. A dry powder inhaler according to Claim 3 wherein the metering member is rotatable from an operable to an inoperable position.

7. A dry powder inhaler according to Claim 1 wherein the metering member comprises a combination of a dispensing member and a moisture sleeve.

8. A dry powder inhaler according to Claim 6 wherein the moisture resistant sleeve acts as a medicament measuring device.

9. A dry powder inhaler according to Claim 1 wherein the device may be moved to a first position in which the medicament is transferred to a measuring chamber, the device is then moved to a second position in which medicament is transferred to a dispensing chamber and to a third position where medicament is delivered to the inhalation passage.

10. A dry powder inhaler according to Claim 1 wherein the dispensing chamber is provided with an air passage.

11. A dry powder inhaler which comprises a medicament reservoir, an inhalation passage for the delivery of the medicament and a metering member adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage characterised in that the metering member comprises a measuring member adapted to measure a pre-defined dosage of medicament and moveable from a measuring to a non-measuring position; and a dispensing member adapted to receive the measured dosage of medicament from the measuring member and to deliver the medicament to the inhalation passage, the dispensing member being moveable from a medicament receiving position to a medicament delivering position.

12. A dry powder inhaler according to Claim 11 wherein the second member is provided with one or more medicament receiving cups, said cups being provided with an air passage so as to provide a flow of air through the passage and the cup into the inhalation passage upon operation of the device.

13. A dry powder inhaler substantially as described with reference to the accompanying drawings.

P36086

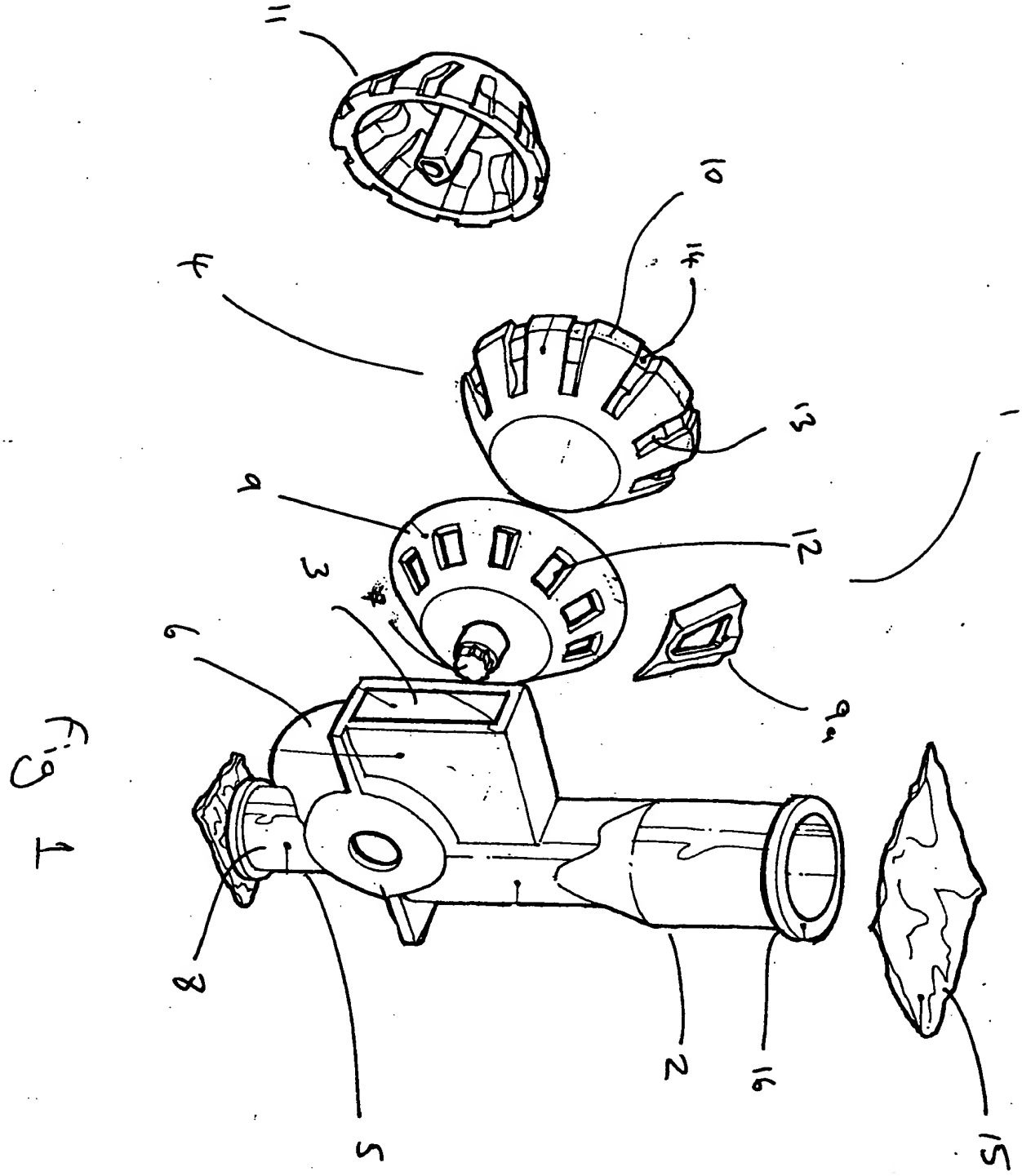
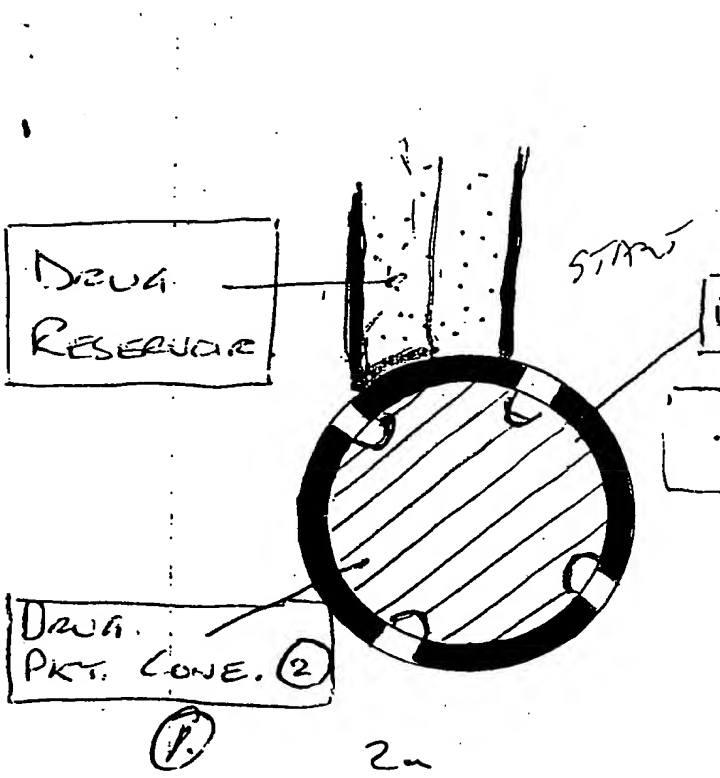
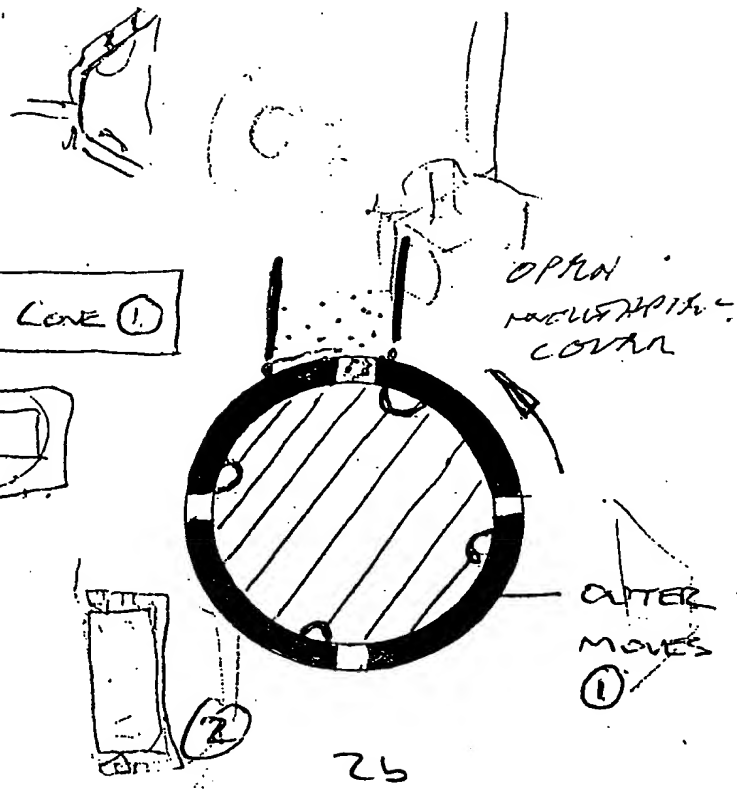


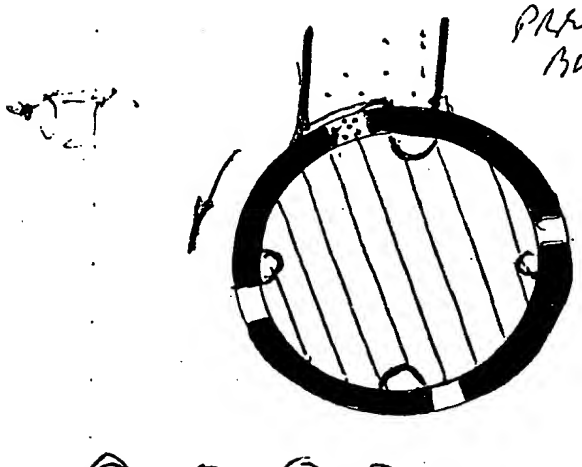
Fig 1



2a

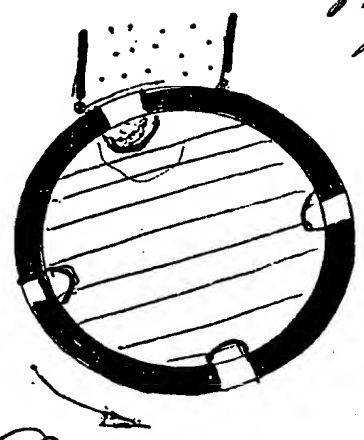


2b



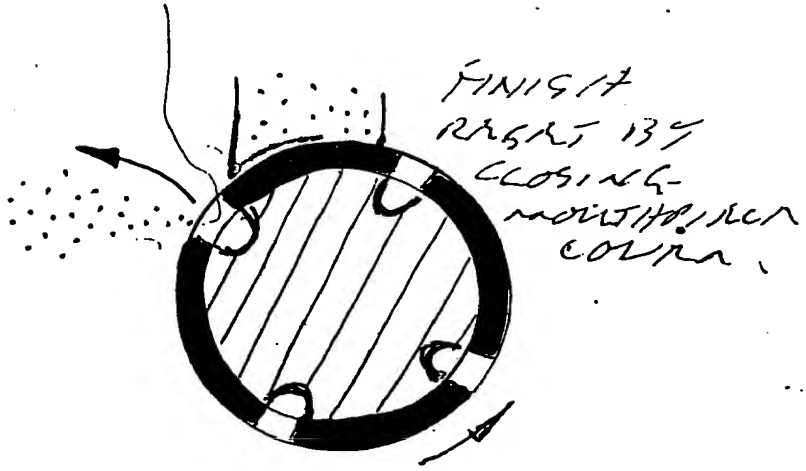
(3) (1) + (2) ROTATE.

2c



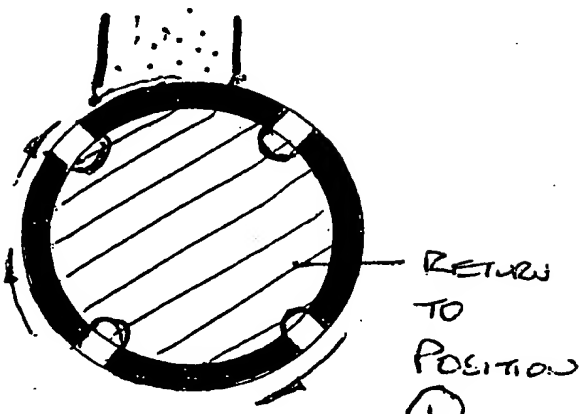
(4) DRUG DROP INTO (2)

2d



(5) DRUG INHALED.

2e



(6) BOTH CONES ROTATE BACK UNTIL

2f

PCT NO : G[redacted]0 / 02017

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Agent : Harrison Goddard Foote